AUG 1 2 2002 K021964

19. 510(k) Summary

510(k) SUMMARY – Safety and Effectiveness

Alpha Infusion Pump

1. Submitters Name:

Advanced Infusion, Inc.
6200 South McClintock #6
Tempe, AZ 85283
(480) 768-9747 (Phone)
Contact: Dr. Reese
Date Prepared: 8-7-02

2. Name of Device:

Trade Name: Alpha Infusion Pump and Catheters
Common Name: Elastomeric Infusion Pump
Classification Name: Pump, Infusion, Elastomeric

3. Predicate Device:

The proposed device, the revised Alpha Infusion Pump and associated Catheters, claims substantial equivalence in intended use and is similar in design, construction, and operation to the currently marketed Alpha Infusion Pump and Catheters (K992551).

4. Description of Device:

The Alpha Infusion Pump is comprised of dual elastomeric chambers which hold the fluid to be infused under pressure. These chambers are contained within a hard shell case. The infusion pump also contains a luer lock checkvalve used to fill the chambers, a 5-micron fluid filter, a hydrophobic air vent filter, a pressure regulator, and an elastomeric septum for attaching infusion catheter(s) to the pump. The infusion pump is packaged as a kit in a tray containing an insertion needle used for placement of the catheter into the patient, a 60cc syringe used to fill the pump, a fabric belt used for holding the pump onto the patient, patient labels, and an Instructions For Use.

The Alpha Cath Infusion Catheters are micro-bore tubing catheters with a needle attached to one end for insertion of the catheter into the infusion pump septum. The internal diameter and length of the catheter tubing acts as the flow restrictor and determines the flow rate of the fluid through the catheter. The infusion catheters are packaged separately in Tyvek pouches and are contained in cartons along with Tegaderm adhesive dressings and an Instruction For Use.

To fill the Alpha Infusion Pump, a 60cc disposable syringe is filled with medication and connected to the female luer lock of the filling checkvalve which is located on top of the

infusion pump. As each syringe of medication is emptied into the elastomeric chambers, the chambers are stretched like a balloon and fill the hard shell outer protective case of the pump. The elastomeric chambers pressurize the medication. The hard shell case restricts the maximum volume that can be filled into the pump.

When filling is complete, the elastomeric chambers force the medication contained within the infusion pump through a 5-micron fluid filter to remove any particulates, through a spring-operated pressure regulator which maintains the medication in the outflow chamber at a constant pressure, and into a delivery chamber having an elastomeric septum. A hydrophobic air vent filter allows any air in the fluid to bleed from the outflow chamber. Infusion catheters of the desired flow rate are inserted through the elastomeric septum in order to deliver medication from the outflow chamber of the infusion pump to the patient.

5. Statement of Intended Use

The Alpha Infusion Pump and associated Catheters are intended for intravenous, intra-arterial, subcutaneous, or epidural infusion of medications or fluids requiring continuous delivery at controlled infusion rates. Medications or fluids are intended to be delivered through a catheter containing a flow restriction element.

The Alpha Infusion Pump and associated Catheters are suitable for use as an ambulatory device and are intended for use in the home environment but not limited to use in the home environment.

6. Comparison to Predicate

Characteristic	Advanced Infusion Device K992551	Advanced Infusion Device (revised)
Pump Type	Elastomeric	Elastomeric
Intended Use	Infusion Pump for delivery of medication or fluid intravenous, intra-arterial, subcutaneous, or epidural	Infusion Pump for delivery of medication or fluid intravenous, intra-arterial, subcutaneous, or epidural
Specific Drugs, Biologics	N/A	N/A
Labeling	Similar	Similar
Components	Infusion Pump 5 micron Filter Hydrophobic Filter Vent Pressure Regulator Flow Restrictor PU Catheter	Infusion Pump 5 micron Filter Hydrophobic Filter Vent Pressure Regulator Flow Restrictor PVC Catheter
Pumping Mechanism	Elastomeric Membrane	Elastomeric Membrane
Admin Sets	Catheter with Polyimide Flow Restrictor	Micro-bore Catheter
Power Required	N/A	N/A
Materials	Polycarbonate	Polycarbonate

	Silicone Elastomer Stainless Steel Nylon Filter PTFE Filter Polyimide Flow Restrictor Polyurethane Catheter	Silicone Elastomer Stainless Steel Versapore Filter PTFE Filter Polyvinyl Chloride Catheter
Flow Rate & Profile	0.5 ml/hr to 10 ml/hr Continuous	0.5 ml/hr to 10 ml/hr Continuous
Safety/Alarms	N/A	N/A
Other Capabilities	N/A	N/A

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 12 2002

Mr. James Christensen
Advanced Infusion, Incorporated
6200 South McClintock, #6
Tempe, Arizona 85283

Re: K021964
Trade/Device Name: Alpha Infusion Pump and Associated Catheters
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: MEB
Dated: June 12, 2002
Received: June 14, 2002

Dear Mr. Christensen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

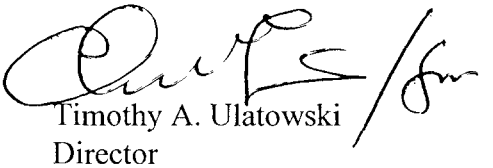
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice

requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K021964

20. Statement of Indications for Use

INDICATIONS FOR USE

510(k) Number (if known):_____

Device Name: Alpha Infusion Pump and associated Catheters

Indications for Use:

The Alpha Infusion Pump and associated Catheters are intended for intravenous, intra-arterial, subcutaneous, or epidural infusion of medications or fluids requiring continuous delivery at controlled infusion rates. Medications or fluids are intended to be delivered through a catheter containing a flow restriction element.

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_____

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K021964